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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,400	12/20/2001	Diana Zanini	VTN-568	3607

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EXAMINER

CHOI, FRANK I

ART UNIT PAPER NUMBER

1616

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/028,400

Applicant(s)

ZANINI ET AL.

Examiner

Frank I Choi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) 25-72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-72 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

In view of the Appeal Brief filed on 3/4/2004, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that claims 1-24 fail(s) to correspond in scope with that which applicant(s) regard as the invention can be found in Appeal Brief filed 3/4/2004. In that paper, applicant has stated that the monomer of formula I

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binds silver (Pg. 4) and argues that one or more of the references do not disclose binding monomers (Pg. 7), and this statement indicates that the invention is different from what is defined in the claim(s) because the claims do not require that the silver be bound specifically to the monomer of formula I.

Claim Rejections - 35 USC § 102

The rejection of claims 1,2,4-9,14-17 under 35 USC 102(b) over JP-05-269181 is withdrawn solely because said reference does not expressly disclose the combination of silver and a monomer of formula I.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 10-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over by JP 05-269181 or EP 1 050 314, each in view of the acknowledged prior art, Vanderlaan et al. (US Pat. 5,998,498) and Laskey (US Pat. 3,929,741).

JP 05-3269181 teaches an antimicrobial soft contact lens comprising an antimicrobial substance, such as an acrylacetate or benzoyl acetate complex of silver, ranging from 0.1 to 20% by weight, polymers of monomers, which include vinyl, allyl group, acrylic groups and/or methacrylic groups, including acryloyloxyethyl phthalic acid, acryloyloxyethyl succinate and methacryloyloxyethyl succinate, phenyl acrylate, phenyl methacrylate, benzy methacrylate and acrylamide (paragraphs 0009-0012, 0024-0026). Specific examples of soft contact lenses are

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taught containing 69.7 w% 2-hydroxyethyl methacrylate, 24.6 w% methyl methacrylate, 0.4 w% ethylene glycol dimethacrylate and 5w% silver acrylacetate or 5w% silver benzoyl acetate (paragraphs 0052-0055). It is taught that the amount of the antibacterial substance to be added depends on the maintenance of transparency and antimicrobial activity (paragraph 0028).

EP 1 050 314 disclose an antimicrobial contact lens containing silver, in an amount such that preferably no other separate disinfection procedure is necessary, where the polymeric material may comprises polymers which are synthetic, naturally occurring, or combination thereof, including silicone polymers, polyolefins, polyesters, poly urethanes, acrylic, hydrogel-forming polymers, polycarbonates and combinations thereof, including poly-HEMA, polyacrylimide, polydimethyl siloxane, PVP, silicone-acrylate or other hydrophilic contact lens material and the like, provided that the polymer or copolymer should be optically clear and otherwise useful as a contact lens material (Paragraphs 0042-0043, 0048, 0051). It is disclosed that the antimicrobial metal ion is present in a concentration from about 0.01 to 5wt. % of the zeolite which is present in the polymer in a concentration of about 0.01 to 5wt.% (Paragraph 0038).

Applicant acknowledges that soft contact lenses based on hydrogels are widely used because they are more comfortable but that extended use encourages the build of bacteria and other microbes (Pg. 1). It is acknowledged that examples of these soft contact lens, include etafilcon A, balafilcon A, aquafilcon A, lenefilcon, lotrafilcon and silicone hydrogels (Pg. 20, lines 1-8).

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Vanderlaan et al. teach that soft contacts can be prepared from silicone hydrogels which combine silicone containing monomers and hydrophilic monomers (See entire reference, especially column 5).

Laskey teaches that hydrophilic monomers of acrylamido sulfonic acid or sulfonate are suitable for soft contact lenses and have greater water retention and because of a greater ability for cross-linking have increased flexibility in the modification of physical properties (Column 1).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose an antimicrobial contact lens comprising silver and a polymer comprising a monomer of formula I. However, the prior art amply suggests the same as antimicrobial soft contact lenses containing silver and monomers falling within the scope of formula I are disclosed by the prior art. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation the soft contact lenses produced would have antimicrobial properties and, thus, avoid the problems associated with extended wear.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the

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references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 208 USPQ 871 (CCPA 1981).

Applicant argues that JP'181 does not disclose a monomer of formula I, however, this is incorrect. The monomers of formula I, for example, where R3 is substituted C1-6alkyl where the substituent is carboxylic acid, where R3 is phenyl or substituted phenyl, and the formula set forth in claims 3, 12, 13, fall within the broad disclosure of suitable monomers as well as specific monomers disclosed in JP '181, as indicated above. Further, as indicated above, contrary to Applicant's arguments, JP'181 does suggest the combination of silver and monomers falling within the scope of formula I. Alternatives for acetate metal complexes is not at issue, as the claims only require that a monomer of formula I and silver be present. There is no requirement in the claims that the silver be specifically bound to the monomer of formula I.

Contrary to Applicant's arguments, (a) acrylamido alkyl sulphonic acid monomers are specifically disclosed to be used in soft contact lenses (Column 3, line 45); (b & c) there is no requirement that Laskey disclose that silver is incorporated in the polymer or that the resulting articles be antimicrobial, this is suggested by JP'181, as indicated above. Contrary to Applicant's arguments, Vanderlaan does include monomer's of formula I within its broad disclosure, as indicated above. Further, in light of the teachings of JP'181 that numerous types of monomers are suitable for the antimicrobial contact lenses, the interchangeability of monomer is suggested by the prior art.

Applicant's arguments with respect to claims 5-9 are moot as the rejection no longer applies to said claims. With respect to Claims 3, 12, 13, as indicated above, JP'181 does include the formula set forth there in within its broad disclosure. Further, Laskey disclose the

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combination of said monomer with other monomers, including that set forth in JP'181 and that the combination exhibits greater water retention and flexibility in the modification of physical properties, as indicated above.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Claims 1,2,4-11,14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over by JP 05-269181 or EP 1 050 314, each in view of the acknowledged prior art and Vanderlaan et al. (US Pat. 5,998,498).

JP 05-3269181, EP 1 050 314, the acknowledged prior art and Vanderlaan et al. are cited for the same reasons as above and are incorporated herein to avoid repetition.

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose an antimicrobial contact lens comprising silver and a polymer comprising a monomer of formula I. However, the prior art amply suggests the same as antimicrobial soft contact lenses containing silver and monomers falling within the scope of formula I are disclosed by the prior art. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation the soft contact lenses produced would have antimicrobial properties and, thus, avoid the problems associated with extended wear.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on

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combinations of references. See *In re Keller*, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 208 USPQ 871 (CCPA 1981).

Applicant argues that JP'181 does not disclose a monomer of formula I, however, this is incorrect. The monomers of formula I, for example, where R3 is substituted C1-6alkyl where the substituent is carboxylic acid, where R3 is phenyl or substituted phenyl, and the formula set forth in claims 3, 12, 13, fall within the broad disclosure of suitable monomers as well as specific monomers disclosed in JP '181, as indicated above. Further, as indicated above, contrary to Applicant's arguments, JP'181 does suggest the combination of silver and monomers falling within the scope of formula I. Alternatives for acetate metal complexes is not at issue, as the claims only require that a monomer of formula I and silver be present. There is no requirement in the claims that the silver be specifically bound to the monomer of formula I.

Applicant's argument's relative to Laskey are considered moot as Laskey is no longer part of the rejection herein and claims 3,12,13 are not rejected herein. With respect to claims 5-9, Applicant has not shown the criticality of the claimed amounts and the prior art, as indicated above, includes said amounts with their broad disclosure.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

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Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over by JP 05-269181 or EP 1 050 314, each in view of the acknowledged prior art and Vanderlaan et al. (US Pat. 5,998,498), in further view of Mueller (US Pat. 5,011,275) or Rostoker et al. (US Pat. 4,038,264).

JP 05-3269181, EP 1 050 314, the acknowledged prior art and Vanderlaan et al. are cited for the same reasons as above and are incorporated herein to avoid repetition.

Mueller discloses a copolymer having high clarity, high hydrophilicity, high oxygen permeability which, in the water swollen state, is soft and flexible, which is suitable for use in soft contact lenses and preferably contains 0.1-10 percent by weight of an ethylenically unsaturated sulfonic acid, such as 2-methacrylamido-2-methyl propane-sulfonic acid (Column 3, Column 4, lines 1-43, Column 12, lines 6-22, Column 6, lines 19-23).

Rostoker et al. disclose that minor amounts of sodium 2-acrylamide-2-methylpropane sulfonic acid, up to 40 percent by weight, to modify the properties of a water-insoluble, hydrophilic polymer which is especially suitable for preparing contact lenses (Column 1, Column 2, lines 1-25, Column 9, Column 10).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose an antimicrobial contact lens comprising silver and a polymer comprising a monomer of formula I. However, the prior art amply suggests the same as antimicrobial soft contact lenses containing silver and monomers falling within the scope of formula I are disclosed by the prior art. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation the soft contact lenses produced would have antimicrobial properties and, thus, avoid the problems

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associated with extended wear and that minor amounts of 2-acrylamide-2methylpropane sulfonic acid can be used to modify the properties of the polymer as desired with the expectation of arriving at a polymer suitable for use in contact lens.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 208 USPQ 871 (CCPA 1981).

Applicant argues that JP'181 does not disclose a monomer of formula I, however, this is incorrect. The monomers of formula I, for example, where R3 is substituted C1-6alkyl where the substituent is carboxylic acid, where R3 is phenyl or substituted phenyl, and the formula set forth in claims 3, 12, 13, fall within the broad disclosure of suitable monomers as well as specific monomers disclosed in JP '181, as indicated above. Further, as indicated above, contrary to Applicant's arguments, JP'181 does suggest the combination of silver and monomers falling within the scope of formula I. Alternatives for acetate metal complexes is not at issue, as the claims only require that a monomer of formula I and silver be present. There is no requirement in the claims that the silver be specifically bound to the monomer of formula I.

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Applicant's argument's relative to Laskey are considered moot as Laskey is no longer part of the rejection herein and claims 3,12,13 are not rejected herein. With respect to claims 5-9, Applicant has not shown the criticality of the claimed amounts and the prior art, as indicated above, includes said amounts with their broad disclosure.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion


A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Thurman Page, can be reached at (571)272-0602. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

FIC

May 13, 2004



THURMAN K. PAGE
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